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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,156	05/30/2000	Lawrence B. Sandberg	97-489-US-P	1346

7590

07/08/2003

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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

15

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/580,156

Applicant(s)

Sandberg

Examiner

Michael Borin

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 6/16/03 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**THE PERIOD FOR REPLY [check only a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attachment

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_
- Claim(s) objected to: \_\_\_\_\_
- Claim(s) rejected: \_\_\_\_\_
- Claim(s) withdrawn from consideration: \_\_\_\_\_
8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☒ Other: PTO 892

MICHAEL BORIN  
PRIMARY EXAMINER  
ART UNIT 1631

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### **ADVISORY ACTION**

1. Amendment after final filed 06/16/2003 is acknowledged.
2. Amendments to the claims are not entered because the proposed claim language "comprising" (see amendments to claims 1,13,19-23) will necessitate further search and new rejections of proteins comprising recited sequences.
3. Accordingly, rejections of claims 1-11,13,19,20-23 under 35 U.S.C. 112, second paragraph, and claim 12 under 35 U.S.C. 102(b), are maintained for the reasons of record (even though the proposed amendment would have overcome these rejections).
4. In regard to claim 13 which is rejected under obviousness-type double patenting, the rejection is maintained for the reasons of record and in view of the following. It is surprising that applicant argues that "claim 13 fails to recite any pharmaceutical application, and merely claims a peptide corresponding to SEQ ID Nos. 42 and 43"<sup>1</sup>. Specification clearly teaches pharmaceutical use of the claimed peptides

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<sup>1</sup>Also, addressing claimed subject matter as a "peptide corresponding to SEQ ID Nos. 42 and 43" is confusing because the proposed amendment do not use the "peptide corresponding ..." language any longer.

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utility. If applicant has in mind some other utility, it is not in the specification and will constitute a new matter. As to the pharmaceutical use, as was stated in the rejection, it is well known in the peptide art to administer peptide in a form of their prodrugs which have protected N- and/or C- termini because such substitution allows to optimize their solubility and/or stability and make them more suitable for pharmaceutical applications. As to the lack of cited secondary references, amide at C-terminal, or acetyl at N-terminal are the most routine substituents used in the peptide art. For example, Borovsky et al. (US Patent 5,358,934) teaches that the derivation of N-terminus and C-terminus of peptides is well known in the art, that the N-terminus and C-terminus of the peptides can be blocked to inhibit proteolysis by metabolic peptides, and that common ways of such protection is acylation of N-terminal or amidation of C-terminal. See paragraph bridging columns 2 and 3.

Thus, Examiner maintains that peptides SEQ ID Nos. 42,43 are obvious variants of earlier patented SEQ ID No. 17. The rejection can be obviated by filing a terminal disclaimer over US 6,069,129.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to

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5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July 7, 2003

MICHAEL BORIN, PH.D  
PRIMARY EXAMINER

mlb

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.